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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,739	02/09/2004	Dean A. Schaefer	1001.1386102	9215
28075	7590	05/14/2009	EXAMINER	
CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			VU, QUYNH-NHU HOANG	
			ART UNIT	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

<b>Application No.</b> 10/774,739	<b>Applicant(s)</b> SCHAEFER ET AL.	
<b>Examiner</b> QUYNH-NHU H. VU	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 25 March 2009.
- 2a)  This action is **FINAL**.
- 2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 16-20 and 22-36 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 16-20 and 22-36 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All   b)  Some \*   c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5)  Notice of Informal Patent Application
- 6)  Other: \_\_\_\_\_.

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**DETAILED ACTION*****Response to Amendment***

Amendment and Request for Continued Examination (RCE) filed on 3/25/09 have been entered.

Claims 16-21, 22-36 are present for examination.

Claims 1-15 and 21 are cancelled.

***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the limitation “**wherein the distal shaft portion has fewer axial members than the proximal shaft portion**” of claim 20 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Applicant states that the support for these claim limitation above can be found at page 5, line 23 through page 6, line 5. Examiner agrees. However, the drawings must show every feature of the invention specified in the claims but the limitation: **wherein the distal shaft portion has fewer axial members than the proximal shaft portion** does not show in the Figs. 2-5.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation “the reinforcement layer is free of crossover points having the first helical member and the second helical member on the same side of the one or more axially extending member” is vague and unclear. The reinforcement layer wrap around catheter with tubular shape, how does Applicant define which side is the same side?

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-20, 22, 24, 29-36 are rejected under 35 U.S.C. 103(a) as being unpatentable by Webster, Jr. (US 5,057,092) in view of Kaye (US 4,191,219).

Regarding claim 16, 33-36, Webster discloses a catheter comprising: an elongate shaft having a reinforcement layer comprising a tubular braid having a first helical member 24 interwoven with a second helical member 26, and a plurality of axial members 28 disposed between the first helical member and the second helical member in some of plurality of crossover points but not each of the plurality of crossover points as in claim 16.

As known that, one skill in the art would recognize that Webster discloses the reinforcement layer is in the interwoven design structure.

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In this case, a fabric woven design is analogous in structure to reinforcement layer of claimed invention. Therefore, the fabric woven design and the reinforcement layer design with interwoven structure are interchangeable and could be used for medical field.

Kaye discloses the fabric interwoven cross construction comprises a first and a second member 16, 18 forming a plurality of crossover point, and a plurality of axial members disposed between the first and second member at each of the plurality of crossover point.

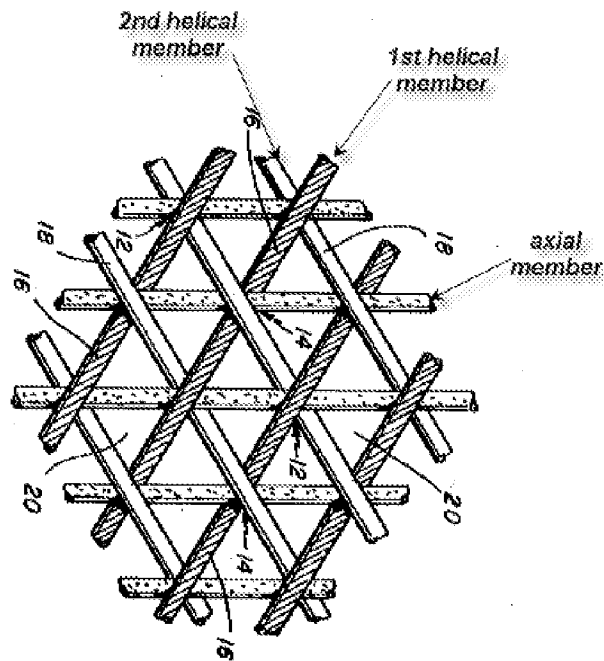
It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Webster with a interwoven cross construction, as taught by Kay, in order to prevent slippage, maximize tear resistance, high torsional stiffness, high resiliency and high flexibility.

However, Webster further discloses that the workers skill in the art and technology to which this invention pertains will appreciate the alterations and changes in described apparatus can be practiced without meaning fully departing from the principals spirits and scope of the his invention (col. 4, lines 17-22).

It would have been an obvious matter of design choice to provide the axial member with different arrangement such as disposed between the first and second helical member at each of the plurality of cross over point. Therefore, it appears that the invention would perform equally well with device of Webster.

Additionally, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e. "for the entire length of the axial member", a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974)

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Regarding claim 17, the axial members are uniformly spaced about the circumference to the shaft.

Regarding claims 18-19, as best as understood, Webster in view of Kaye discloses the claimed invention (see rejection above). Webster in view of Kaye does not clearly show that four axial members are uniformly spaced apart by  $90^\circ$  about the circumference of the shaft; eight axial members are uniformly spaced apart by  $45^\circ$  about the circumference of the shaft. It would have been an obvious matter of design choice to provide the axial members as listed above, since applicant has not disclosed that the number of axial members spaced apart by  $45^\circ$  or  $90^\circ$  solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the device of Webster.

Regarding claim 20, Webster discloses, in Fig. 1, the elongate shaft includes a proximal portion and a distal portion, and wherein the distal shaft portion has fewer axial members 28 than the proximal shaft portion.

Furthermore, it is noted that those skilled in the art will recognize that if an inner diameter of the proximal shaft is larger than an inner diameter of distal shaft portion will give the same result that the distal shaft portion has fewer axial members than the proximal shaft portion. For example, Head (US

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6,148,865) is one of evidence shows that the distal shaft portion has fewer the axial members 22 the proximal shaft (see Fig. 3A); or Osborne (US 5,251,640) shows that the distal shaft portion has fewer the axial members 12 the proximal shaft (Figs. 1-5).

Not only that, the cross section area or diameter of distal portion of catheter is smaller than proximal portion is very well-known in the catheter art.

It would have been an obvious matter of design choice to provide the axial members as listed above, since applicant has not disclosed that the number of axial members solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the device of Webster.

Regarding claims 22 and 24, the first and second helical members each comprise polymer material (col. 2, lines 54-65).

Regarding claim(s) 29-32, they encompass the same scope of the invention as to that of claims 16-19 above except they are drafted in method format instead of apparatus format. The claim(s) is/are therefore rejected for the same reason as set forth above.

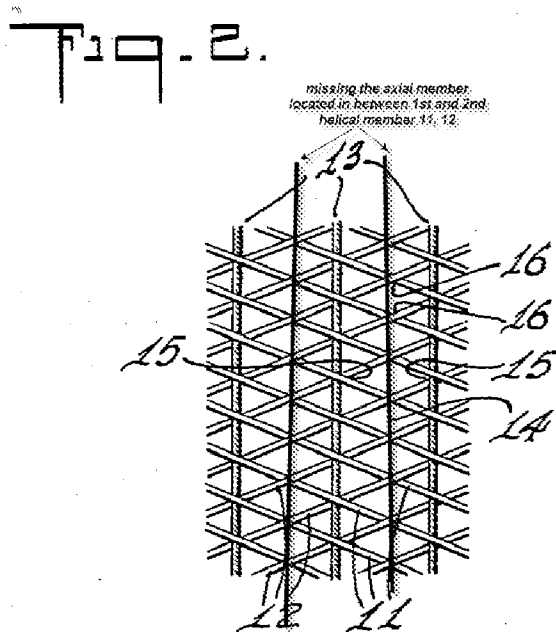
Claims 16-20, 22, 24, 29-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huppert (US 2,114,274).

Regarding claims 16-17, 33-36, Huppert discloses the tubular braid for use among other purpose. In this case, a medical article such as a catheter tube is analogous in structure to tubular braid of Huppert. Therefore, the braid tubular and the catheter tube are interchangeable and can be used in catheter arts as it relates with the tubular.

Huppert discloses that device comprising an elongated shaft having a reinforcement/braid layer comprising a tubular braid having a first and second helical member 11, 12 and plurality of axial members 13 disposed between the first and second helical member at some of the plurality of crossover points but not at each of the plurality of crossover points as in claim 16. In other words, there is missing of some of axial members located in between the first and second members as shown in Fig. 2 below.

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It would have been an obvious to one of ordinary skill in the art at the time the invention was made to add more axial member for the purpose of increasing the reinforcing or torsional rigidity.



Regarding claims 18-20, similarly to the rejection of claims 18-20 under Webster in view of Kaye above.

Regarding claims 22, 24, Huppert discloses the claimed invention except for the first second members and axial members formed of polymeric material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the helical and axial members formed of polymeric material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding claim(s) 29-32, they encompass the same scope of the invention as to that of claims 16-19 above except they are drafted in method format instead of apparatus format. The claim(s) is/are therefore rejected for the same reason as set forth above.



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Claims 23 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster, Jr. (US 5,057,092) in view of Kaye (US 4,191,219) or Huppert and further in view of Mortier et al. (US 5,730,733).

Webster in view of Kaye or Huppert discloses the claimed invention (see rejection above).

Webster in view of Kaye does not disclose that the first and second helical members each comprise a plurality of monofilaments; wherein the monofilaments comprise LCP; the monofilaments are arranged side-by-side to collectively define a flat ribbon.

Mortier discloses that a first and second helical members 32 or 34 (Fig. 2A) each comprises a plurality of monofilaments 26, 36; wherein the monofilaments comprise LCP (liquid crystal polymer material), (col. 4, lines 18-30); the monofilaments are arranged side-by-side to collectively define a flat ribbon.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Webster in view of Kaye or Huppert with a plurality of monofilaments, as taught by Mortier, in order of increase the torsional rigidity and more flexible.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 16-32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent Nos. 6,709,429.

Claims 16, 22-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 6-9, 11, 13-28 of U.S. Patent Nos. 6,942,654.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the device and method of instant claims are fully disclosed and covered by the claims in the U.S. patents. 6,709,429 and 6,942,654.

### ***Response to Arguments***

Applicant's arguments with respect to claims 16-20, 22-36 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu  
Examiner  
Art Unit 3763